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In re Application of	:
Alan N. Houghton et al.	:
Serial No.: 09/996,128	: PETITION DECISION
Filed: November 27, 2001	:
Attorney Docket No.: MSK.P-026-3	:

This letter is in response to the petition under 37 CFR 1.144, filed February 27, 2007, requesting review and modification of the restriction requirement. The delay in acting upon this petition is regretted.

BACKGROUND

A review of the file history shows that this application was filed on November 27, 2001, under 35 U.S.C. 111(a). The examiner mailed to applicants on June 25, 2004, a restriction requirement, wherein six distinct inventions (Groups I-VI) were identified and rationale set forth establishing the examiner's position.

> Group I, drawn to a method for treating melanoma by administering human tyrosinase.
> Group II, drawn to a method for treating melanoma by administering human gp75.
> Group III, drawn to a method for treating melanoma by administering mouse tyrosinase.
> Group IV, drawn to a method for treating melanoma by administering mouse gp75.
> Group V, drawn to a vector comprising SEQ ID No 1.
> Group VI, drawn to a vector comprising SEQ ID No 2.

Applicants' replied on July 26, 2004, electing Group I, with traverse. Applicants argued that election should be treated as an election of human tyrosinase as a species and that the claims of Groups II, III and IV should be recombined.

The examiner mailed a new Office action on November 3, 2004, acknowledging the election of Group I and the traversal. The examiner maintained the requirement and made it Final on the basis that the differentiation antigens are patentably distinct and structurally different from one another and would elicit different immune responses. Claims 3, 6-9, 13-16, 18 and 25-27 were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claims 1, 2, 4, 5, 10, 11 and 19-23 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 1, 2, 4, 5, 10-12 and 19-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Disis et al. in

view of Naftzger et al. Claims 1, 2, 4, 5, 10-12, 17 and 19-24 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/041,410.

On February 3, 2005, applicants responded with arguments addressing all outstanding rejections of record appropriately.

On May 6, 2005, the examiner mailed to applicants a second Non-Final Office action. The rejection of claims 1, 2, 4, 5, 10, 11 and 19-23 under 35 U.S.C. 112, first paragraph, was withdrawn in view of applicants' arguments. The rejection of claims 1, 2, 4, 5, 10-12 and 19-23 under 35 U.S.C. 103(a) as being unpatentable over Disis et al. in view of Naftzger et al. was withdrawn in view of applicants' arguments. Claims 1, 4, 10, 11, 19, 20 and 23 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. The provisional rejection of claims 1, 2, 4, 5, 10-12 and 19-23 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/041,410 was maintained. Claims 17 and 24 were objected to as being dependent upon a rejected base claim.

Applicants filed a response on August 7, 2005, adding claims 28-29 and appropriately responding to the rejections/objections of record.

On November 1, 2005, the examiner mailed to applicants a third Non-Final Office action. Upon reconsideration, the examiner rejoined Group II (claims 1, 3, 4, 6, 10, 11, 13, 19, 20, 23 and 24, to the extent the claims read upon human gp75) with the elected Group I. Claims 3, 7-9, 14-16 and 25-27 were withdrawn from consideration as being drawn to a non-elected invention. Claims 28 and 29 were objected to for referring to non-elected subject matter. Claims 1-6, 10, 11, 19, 20, 21, 23, 28 and 29 were rejected under 35 U.S.C. 112, first paragraph, for lack of enablement. Claims 1, 4, 10 and 11 were rejected under 35 U.S.C. 102(a) as being anticipated by Zhai et al. Claims 1-6, 10-13 and 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zhai et al. in view of US 5,773,291. The provisional rejection of claims 1, 2, 4, 5, 10-12, 17 and 19-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/041,410 was maintained.

Applicants filed a response on May 1, 2006, canceling claims 1-19 and 28; adding claim 30; and appropriately addressing the rejections of record.

On July 18, 2006, the examiner mailed to applicants a fourth Non-Final Office action. The objection to claim 28 was withdrawn. The rejection of claims 20, 21, 23 and 29 under 35 U.S.C. 112, first paragraph, for lack of enablement was withdrawn. The rejection of claims 1, 4, 10 and 11 under 35 U.S.C. 102(a) as being anticipated by Zhai et al. was withdrawn. The provisional rejection of claims 20-24 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/041,410 was withdrawn. Claims 20-23 and 29-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Zhai et al. in view of US 5,773,291 and US 6,080,727.

Applicants filed a response on October 18, 2006, amending claim 24 and appropriately addressing the rejections of record.

On December 27, 2006, the examiner mailed to applicants a Final Office action. Claims 25-27 were withdrawn from consideration as being drawn to a non-elected invention. The rejection of claims 20-23, 29 and 30 under 35 U.S.C. 103(a) as being unpatentable over Zhai et al. in view of US 5,773,291 and US 6,080,727 was maintained. Claim 24 was allowed.

Applicants filed a response to Final Office action February 27, 2007, along with this petition. The examiner has not yet responded to the amendment after Final Office action pending this petition decision.

DISCUSSION

The petition and filed history have been carefully considered.

Applicants argue that (1) MPEP 803.04 indicates that election of up to ten species of oligonucleotide per application is reasonable even in the context of a composition claim, in accordance with the partial waiver of the single invention provisions of 37 CFR 1.141. Applicants also argue that (2) the examiner has not shown a search burden. As third point to be considered, the application contains linking claim, which, if allowable, would result in withdrawal of the restriction requirement between the linked inventions.

1. Consideration of MPEP 803.04 in view of the March 27, 2007 OG Notice.

The petition asserts that the examination is inconsistent with Manual of Patent Examining Procedure (MPEP) 803.04. The petition states that the restriction improperly limited election to only one nucleotide sequence, instead of 10 nucleotide sequences and limited examination to only the one elected sequence together with only two patentably indistinct sequences instead of all antisense oligonucleotides corresponding to a single gene encoding a single protein. The petition cites MPEP 803.04 directed to the 1996 OG Notice, which granted a partial waiver for independent and distinct inventions. This argument has been reviewed but is not convincing.

An OG Notice published March 27, 2007 rescinded the 1996 OG Notice that provided for a partial waiver of the requirements for restriction practice by permitting examination of a reasonable number, up to ten, independent and distinct polynucleotide molecules in a single 35 USC 111(a) or 35 USC 371 application. The Notice indicated that the standard of independence and distinctness would be applied to polynucleotide claims filed in an application under 35 USC 111(a).

2. Consideration of Burden

Additionally, the March 27, 2007 OG Notice specifically spoke to the issue of burden of searching more than one independent and distinct invention. The instantly claimed embodiments have a different field of search and require different database queries. The advances in nucleic acid sequencing techniques have lead to the exponential growth in the size of nucleic acid sequence databases and an increase in the number and complexity of such databases. These factors exacerbate the search and examination burden faced by the office with respect to

polynucleotide inventions claimed and described in currently filed applications. Due to the vast number of sequences presently listed in the database, search and examination of multiple combinations nucleotide sequences causes an undue burden upon the examiner and the Office.

2. Consideration of Linking Claims

MPEP 809 provides direction for linking claims. MPEP 809 specifically states "[l]inking claims and the inventions they link together are usually either all directed to products or all directed to processes (i.e., a product claim linking properly divisible product inventions, or a process claim linking properly divisible process inventions)."

Claim 20 is a linking claim because it is not specific for any particular xenographic differentiation antigen. The Xenographic differentiation antigen may be human or mouse tyrosinase or human or mouse gp75.

> **20. (original) A method for treating canine malignant melanoma in a dog suffering from canine malignant melanoma comprising administering to the dog an immunologically-effective amount of a xenogeneic differentiation antigen of the same type as a differentiation antigen expressed by melanoma cells of the dog.**

In this application, the examiner has properly treated the linking claim 20. The generic linking claim has been examined on its merits and is currently rejected under 35 USC 103(a). At this point, the linking claim is not in condition for allowance. Any request for rejoinder among linked species or linked inventions would be premature until all claims directed to the elected invention, including all linking claims are in condition for allowance.

The MPEP further provides that

> "Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.
>
> Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

DECISION

The petition is **GRANTED-IN-PART**.

The petition is **GRANTED** to the extent that Claim 20, as currently drafted, will continue to be treated as a linking claim. The examiner will continue to examine the linking claims on the merits as long as claim 20 encompasses the elected invention. In the event that all the generic claims directed to the elected invention become allowable, the examiner will reconsider rejoinder of claims which depend from or otherwise all the limitations of allowable claims, including any directed to non-elected sequences.

The request to withdraw the restriction requirement made between the method administering a vector having SEQ ID No 1 (which encodes human tyrosinase, as encompassed by claims 20-24, 29 and 30) and SEQ ID NO 2 (which encodes mouse tyrosinase set forth in claim 25) is **DENIED** as premature, in view of the unpatentability of linking claim 20.

The restriction requirement Group I and II was withdrawn by the examiner in the Office action mailed 1 November 2005. The method of administering human tyrosinase and method of administering human gp75 are currently under examination.

The restriction requirement set forth between the method of administering human or mouse tyrosinase (Groups I and III) and the product of a vector encoding human or mouse tyrosinase (Groups V and VI) is maintained.

Applicants remain under obligation to respond to the FINAL Office action mailed 27 December 2006 or to take other appropriate action within the time period set forth in that FINAL Office action.

Any request for reconsideration of this decision must be filed within two (2) months of the mailing date of this decision.

The application will be forwarded to the examiner for further action consistent with this decision and for consideration of applicants' response filed 27 February 2007 along with this petition.

Should there be any questions about this decision, please contact Quality Assurance Specialist/Program Manager Julie Burke, by letter addressed to Director, Technology Center 1600, at the address listed above, or by telephone at 571-272-1600 or by facsimile sent to the general Office facsimile number, 571-273-8300.

John LeGuyader
Director, Technology Center 1600